MAY 31 2002

K020033

Special 510(k) Summary

Contact Information: Surgica Corporation
5090 Robert J. Mathews Pkwy., #4
El Dorado Hills, CA 95762
Telephone: 1(916) 933-5056
Facsimile: 1(916) 933-5260
Contact Person: Lou Matson

Trade Name: MaxiStat™ Polyvinyl Alcohol Foam Embolization Particles

Common Name: PVA Foam Embolization Particles

Classification Name: Artificial Embolization Device

Device Product Code: HCG

Regulation Number: 882.5950

Substantial Equivalence: The Surgica Corporation MaxiStat™ Polyvinyl Alcohol Foam Embolizaion Particles are similar in their basic design, construction, indication for use, and performance characteristics to other commercially available polyvinyl alcohol particles.

Device Description: Surgica Corporation MaxiStat™ Polyvinyl Alcohol (PVA) foam embolization particles are artificial embolization devices used to obstruct or reduce the blood flow to hypervascular or neoplastic lesions via superselective catheter delivery. The embolization particles are supplied in various size ranges to enable appropriate size selection for the lesion to be treated. Polyvinyl Alcohol (PVA) foam embolization particles are designed to be delivered under fluoroscopic guidance through compatible infusion catheters. The product is delivered sterilized with radiation, is nonpyrogenic, and is for single use only.

Indications For Use: The MaxiStat™ Surgica Corporation Polyvinyl Alcohol Foam Embolizaion Particles may be used for vascular occlusion of blood vessels within the neurovascular systems. They are intended for use in the endovascular management of arteriovenous malformations (AVMs) and neoplastic lesions when presurgical devascularization is desirable.

Predicate Devices: The EMB™ PVA Foam Embolization Particle devices marketed by Surgica Corporation (K001678) represent is the predicate device for the Surgica Corporation MaxiStat™ Polyvinyl Foam Embolizaion Particles.

Clinical Tests: None

Adverse S&E Information: None

Louis R. Matson

Louis R. Matson
President & C.E.O.

12-31-01

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

Mr. Louis R. Matson
President and C.E.O.
Surgica Corporation
5090 Robert J. Mathews Parkway, #4
El Dorado Hills, CA 95762

Re: K020033
Trade/Device Name: PVA Foam Embolization Particles
Regulation Number: 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: April 30, 2002
Received: May 1, 2002

Dear Mr. Matson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020033

Device Name: PVA Foam Embolization Particles

Indications For Use:

The Surgica Corporation MaxiStat™ PVA Foam Embolization Particles are intended for the following indication:

PVA particles may be used for vascular occlusion of blood vessels within the neurovascular systems. They are intended for use in the endovascular management of arteriovenous malformations (AVMs) and neoplastic lesions when presurgical devascularization is desirable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020033

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)